REMARKS/ARGUMENTS

Claims 14, 15, 18 through 20, 22, 23, 32 through 34, 36 through 43 and 45 through 51are pending in the application

Claim 35 has been canceled.

No amendments of the claims have been made at this time.

A Notice of Appeal and appropriate extensions of time were timely filed on March 15, 2007. We hereby request a two month extension of time and a Request for Continued Examination with the appropriate fees are hereby timely filed with this response.

In lieu of filing an Appeal Brief, Applicant is hereby filing a Request for Continued Examination application (an RCE) that addresses the outstanding issues of the Office Action made Final, dated September 15, 2006.

Applicant respectfully requests that the following remarks be considered in view of the Office Action made Final.

Claim Objections

Claim 35 is objected to under 37 C.F.R. § 1.75 as being an exact duplicate of claim 34.

Claim 35 has been canceled, thereby obviating the basis for the rejection. Applicant apologizes for the oversight in that claim 35 had been previously canceled and then reappeared in a subsequent response.

Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection of Claims 14, 15, 18 through 20, 22, 23, 32 through 34, 36 through 43 and 45 through 51 Under 35 USC § 103(a)

Claims 14, 15, 18 through 20, 22, 23, 32 through 34, 36 through 43 and 45 through 51 stand rejected under 35 USC 103(a) as being unpatentable over U.S. Patent Publication No.

2005/0025756 Erwin (hereinafter "Erwin") further in view of Soft Gel Technologies, Inc. EP 888774 (hereinafter "Soft Gel") and U.S. Patent Publication No. 2004/0001874 Davidson et al. (hereinafter "Davidson"). Applicant respectfully traverses the rejection for at least the following reasons.

To begin, the present invention pertains to a soft gelatin capsule that includes coenzyme Q-10 ***solubilized*** (dissolved) in limonene. The present invention also pertains to packaged neutraceuticals for the administration of solubilized coenzyme Q-10 in a soft gelatin capsule. This is the crux of the invention.

The soft gelatin capsule can ***optionally*** further include a carrier, such as bee's wax, rice bran oil, or a fish oil. The soft gelatin capsule can ***optionally*** also further include an antioxidant. These optional components are subsumed by dependent claims; they are not included in the independent claims as the Office Action appears to make reference to on multiple occasions. This is an incorrect interpretation of the broadly claimed subject matter.

The references of record will now be addressed.

Erwin, to some degree, discloses the use of monoterpenes, such as limonene to dissolve coenzyme Q-10. The formulations Erwin discloses are liquid formulations.

Erwin fails to teach or suggest, fails to provide any motivation or an expectation of success to a person having ordinary skill in the art of any delivery means other than as a free flowing liquid, such as a syrup or elixir. Erwin is completely devoid of any teaching or suggestion, or providing any motivation or an expectation of success to a person having ordinary skill in the art to prepare a soft gelatin capsule that would encapsulate solubilized coenzyme Q-10. Such a suggestion simply does not exist in Erwin.

Erwin fails to teach or suggest, provide any motivation or an expectation of success to one of ordinary skill in the art that a solubilized solution of limonene and coenzyme Q-10 could be encapsulated ***within a soft gelatin capsule***. Absent a teaching, suggestion, or providing

motivation to a skilled artisan, no reference can make obvious something, which is not contemplated by the reference. As such, Erwin fails to appreciate that liquid limonene/coenzyme Q-10 could be encapsulated into a soft gelatin capsule.

Soft Gel fails to remedy the deficiencies of Erwin, alone or in combination.

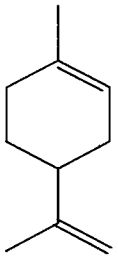
Soft Gel discloses use of rice bran oil or Vitamin E to suspend coenzyme Q-10 in the carrier (rice bran oil or Vitamin E), which is formulated, into a soft gelatin capsule. Soft Gel does not teach or suggest that the rice bran oil or Vitamin E solubilizes (dissolves) coenzyme Q-10.

Soft Gel is completely devoid of any teachings **of any carrier other than rice bran oil or Vitamin E**. In fact Soft Gel doesn't provide any teaching or suggestion, an expectation of success or any reason to a person having ordinary skill in the art to try any other carriers. Therefore, the teachings of Soft Gel are very limited in this respect.

Soft Gel fails to teach or suggest, provide any reason or an expectation of success to a person having ordinary skill in the art to select a monoterpene, such as limonene, as a carrier ***for any ingredient***.

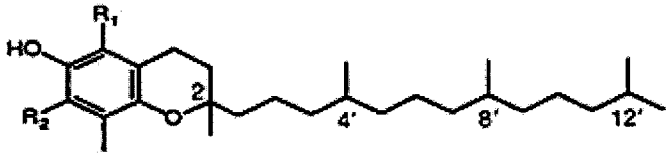
Moreover, Soft Gel fails to teach or suggest, provide any reason or an expectation of success to a person having ordinary skill in the art that limonene would be a good solubilizing agent for coenzyme Q-10. A fair reading of Soft Gel would not provide any teaching, suggestion or reason to a person having ordinary skill in the art to substitute rice bran oil or Vitamin E with anything other carrier other than rice bran oil or Vitamin E.

Limonene, Vitamin E and rice bran oil are chemically dissimilar in chemical composition.

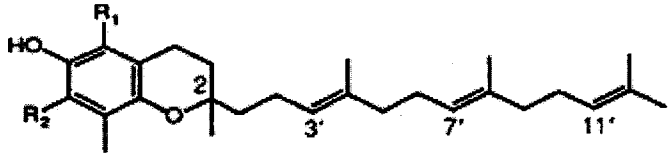
Limonene is a monocyclic terpene having the formula  .

Limonene, therefore, is a an unsaturated cyclic hydrocarbyl. It is completely devoid of any other functionality other than two degrees of unsaturation. It is hydrocarbon like. Limonene is a **non-polar substance**.

Vitamin E is a mixture of four different tocopherols (α-, γ, δ, and β-tocopherols) and four corresponding tocotrienols:



R^1	R^2	
CH_3	CH_3	α-Tocopherol
CH_3	H	β-Tocopherol
H	CH_3	γ-Tocopherol
H	H	δ-Tocopherol



R^1	R^2	
CH_3	CH_3	α-Tocotrienol
CH_3	H	β-Tocotrienol
H	CH_3	γ-Tocotrienol
H	H	δ-Tocotrienol

Tocopherols include a hydroxyl group (phenolic site) and an ether linkage. These are **polar groups**.

The typical composition of rice bran oil is 81.3-84.3% triglycerides, 2-3% diglycerides, 5-6% monoglycerides, 2-3% free fatty acids, 0.3% waxes, 0.8% glycolipids, 1.6% phospholipids, and 4% unsaponifiables. The fatty acid components of the glycerides are myristic, palmitic, stearic, oleic, linoleic, linolenic, arachidic, and behenic acids. Obviously, rice bran oil contains **many polar groups**.

As should be noted, limonene has no carboxylic acid (or esters), no phenolic and no ether components as do the fatty acids of rice bran oil, and Vitamin E (respectively). Moreover, Vitamin E and rice bran oil are combinations of components, whereas limonene is a single material.

There is simply no teaching or suggestion, expectation of success or reason provided to a person having ordinary skill in the art to interchange such carriers, having vastly different physical properties in terms of functionality and/or polarity in view of the differences between limonene versus rice bran oil or Vitamin E.

Davidson does not remedy the deficiencies of any of the aforementioned references, alone or in combination.

Davidson teaches much the same as Soft Gel, in that coenzyme Q-10 can be formulated in fish oil in a soft gelatin capsule. Again, it is not known whether the fish oil solubilizes the coenzyme Q-10 or merely suspends the coenzyme Q-10.

Fish oil has as its major components, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). The are polyunsaturated fatty acids or glycerides thereof. Again, these compounds contain carboxylic acids (or esters) and do not have similar structural characteristics akin to that of limonene. Again, fish oil is a combination is a combination of at least two (2) components, whereas limonene is a single material. Limonene is an unsaturated cyclic hydrocarbyl. It is completely devoid of any other functionality other than two degrees of unsaturation.

Davidson is completely devoid of teaching or suggestion, providing any reason or an expectation of success to a person having ordinary skill in the art that any carrier other than fish oil would be a suitable substitute to solubilize coenzyme Q-10.

As noted above, the constitution of fish oil and limonene are chemically dissimilar.

There is no teaching or suggestion, expectation of success or reason that a person having ordinary skill in the art would consider that limonene and fish oil could be interchangeable as a carrier for coenzyme Q-10. There is simply no teaching or suggestion, expectation of success or

reason such that a person having ordinary skill in the art would rely on Davidson to substitute limonene for fish oil.

Davidson s fails to mention limonene.

Davidson fails to mention the combination of a carrier and limonene.

Davidson fails to mention the combination of a carrier and limonene where coenzyme Q-10 remains dissolved.

A person having ordinary skill in the art would not look to Davidson for any teaching that would have to do with mixing coenzyme Q-10 with a sufficient quantity of limonene suitable to solubilize the coenzyme Q-10 with an acceptable carrier to form a composition in which the coenzyme Q-10 remains dissolved. Nor would a person having ordinary skill in the art look to Davidson to provide the requisite teaching or suggestion, reason or an expectation of success to then encapsulate the limonene/carrier/coenzyme Q-10 composition (in which the coenzyme Q-10 remains dissolved) into a soft gelatin capsule.

Davidson fails to teach or suggest, provide any reason or an expectation of success to a person having ordinary skill in the art to mix coenzyme Q-10 with a sufficient quantity of limonene suitable to solubilize the coenzyme Q-10 with an acceptable carrier to form a composition in which the coenzyme Q-10 remains dissolved. Davidson fails to provide the requisite teaching or suggestion, reason or an expectation of success to a person having ordinary skill in the art to then encapsulate the limonene/carrier/coenzyme Q-10 composition (in which the coenzyme Q-10 remains dissolved) into a soft gelatin capsule.

Consequently, none of the references, alone or together, teach or suggest, provide any reason or an expectation of success to a person having ordinary skill in the art to mix coenzyme Q-10 with a sufficient quantity of limonene suitable to solubilize the coenzyme Q-10 with an acceptable carrier to form a composition in which the coenzyme Q-10 remains dissolved. None of the references, alone or in combination thus provides the requisite teaching or suggestion, reason or an expectation of success to a person having ordinary skill in the art to then

encapsulate the limonene/carrier/coenzyme Q-10 composition (in which the coenzyme Q-10 remains dissolved) into a soft gelatin capsule.

The Office Action made Final is inappropriately applying hindsight analysis to the problem to be solved and the invention. This application of impermissible hindsight is not allowed under current patent law as noted below.

> As in all determinations under 35 U.S.C. section 103, the decision-maker must bring judgment to bear. It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps. *In re Gorman*, 933 F.2d 982 (Fed. Cir. 1991)

> "Virtually all [inventions] are combinations of old elements." Therefore, an Examiner may often find every element of a claimed invention in prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejection patents solely by find prior art corollaries for the claimed elements would permit an Examiner to use the claimed invention itself as a blue print for piecing together elements in the prior art to defeat patentability of the claimed invention. To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test of obviousness. *Yamanouchi Pharmacutical Co. v. Danbury Pharmacal Inc.*, 231 F. 3d 1339 (Fed. Cir. 2000)

It is legally impermissible to take the teachings of Erwin, Soft Gel and Davidson and combine them with the benefit of hindsight analysis.

Moreover, in the recent case of *Takeda Chem. Indus. v. Alphapharm Pty. Ltd.,* 2007 U.S. App. LEXIS 15349 (Fed. Cir. June 28, 2007), the Federal Circuit found that

> ...it remains necessary to identify some reason that would have led a chemist to modify a known compound.....to establish prima facie obviousness...

There is simply no reason provided that a chemist would first choose the cited references, then combine the references in a way to arrive at the claimed invention. There are a myriad of

possibilities as to what the combination of references could provide. Selection of components and then encapsulating whatever the components would be into a soft gelatin capsule is not provided without the guidance of legally impermissible hindsight. Moreover, the selection of components could have led a chemist to a combination of, for example, coenzyme Q-10 in a carrier such as fish oil used in an elixir or in a topical composition as a cream, especially in view of the teachings of the primary reference, Erwin....not a soft gelatin capsule and hence, not encapsulated in any manner.

To further reinforce the last point, the sole example provided by Erwin includes cetyl myristoleate, a wax. It is noted that the specification provides that the formulation may solidify!...and that the solidified material can be **resolubilized** by heating to 37 degrees centigrade! (Paragraphs 48 through 50.) This certainly does not provide a teaching, motivation or a reason for a chemist to select components for a soft gelatin capsule that provides a solubilized coenzyme Q-10...that does not require resolubilization. A reasonable reading of this example actually provides a teaching away of from the present invention where the coenzyme Q-10 remains **solubilized**...an important aspect of the present invention.

If perhaps the term solubilized is not acceptable to the Examiner, Applicant would offer the term "dissolved" to help clarify that the coenzyme Q-10 is dissolved and does not precipitate from solution while encapsulated within the soft gelatin capsule.

Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the above, Applicant respectfully submits that the present application is in condition for allowance. Reconsideration of the present application and a favorable response are respectfully requested.

If a telephone conference would be helpful in resolving any remaining issues, please contact the following at 612-340-8819.

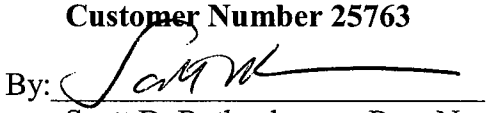
This response is being submitted on or before July 12, 2007, with the required fee of $620.00, which includes $225.00 for a two-month extension of time and $395.00 for a Request for Continued Examination (RCE) filed herewith, making this a timely response. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

Respectfully submitted,

DORSEY & WHITNEY LLP

Customer Number 25763

Date: July 12, 2007

By: 

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